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PFIZER INC., PHARMACIA CORPORATION
AND G.D. SEARLE LLC

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

IN RE BEXTRA AND CELEBREX
MARKETING, SALES PRACTICES AND
PRODUCTS LIABILITY LITIGATION

This document relates to

TIM GRAY,

Plaintiff,

vs.

PFIZER, INC., PHARMACIA CORPORATION,
G.D. SEARLE LLC and MONSANTO
COMPANY,

Defendants.

) MDL Docket No. 1699

) CASE NO. 3:08-cv-01434-CRB

) **PFIZER INC., PHARMACIA**
) **CORPORATION, AND G.D.**
) **SEARLE LLC'S ANSWER TO**
) **COMPLAINT**

) **JURY DEMAND ENDORSED**
) **HEREIN**

NOW COME Defendants Pfizer Inc. (improperly captioned in Plaintiff's Complaint as "Pfizer, Inc.") ("Pfizer"), Pharmacia Corporation (f/k/a Monsanto Company) ("Pharmacia") and G.D. Searle LLC ("Searle") and file this Answer to Plaintiff's Complaint ("Complaint"), and would respectfully show the Court as follows:

I.

PRELIMINARY STATEMENT

The Complaint does not state in sufficient detail when Plaintiff was prescribed or used Celebrex® (celocoxib) (“Celebrex®”). Accordingly, this Answer can only be drafted generally. Defendants may seek leave to amend this Answer when discovery reveals the specific time periods in which Plaintiff was prescribed and used Celebrex®.

II.

ORIGINAL ANSWER

Response to Allegations Regarding Parties

1. Defendants admit that Plaintiff brought this civil action seeking monetary damages, but deny that Plaintiff is entitled to any relief or damages. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

2. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff’s age or state of residence and, therefore, deny the same.

3. Defendants admit that Pfizer, Pharmacia, and Searle do business in the State of Minnesota. Defendants state that the remaining allegations in this paragraph of the Complaint assert legal contentions to which no response is required. To the extent that a response is deemed required, Defendants deny the remaining allegations in this paragraph of the Complaint.

4. Defendants admit that Pfizer is a Delaware corporation with its principal place of business in New York. Defendants admit that Pfizer is registered to do business in the State of Minnesota. Defendants admit that Pfizer may be served through its registered agent. Defendants admit that Pharmacia acquired Searle in 2000 and that, as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer. Defendants admit that, during certain periods of time, Pfizer and Pharmacia co-promoted and marketed Celebrex® in the United States, including Minnesota, to be prescribed by healthcare providers who are by law authorized

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1 to prescribe drugs in accordance with their approval by the FDA. Defendants state that
2 Plaintiff's allegations regarding "predecessors in interest" are vague and ambiguous. Defendants
3 are without knowledge or information to form a belief as to the truth of such allegations, and,
4 therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the
5 Complaint.

6 5. Defendants admit that Searle is a Delaware limited liability company with its
7 principal place of business in Illinois. Defendants admit that Pharmacia acquired Searle in 2000
8 and that, as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of
9 Pfizer. Defendants admit that, during certain periods of time, Celebrex® was manufactured and
10 packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex®
11 in the United States to be prescribed by healthcare providers who are by law authorized to
12 prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining
13 allegations in this paragraph of the Complaint.

14 6. Defendants admit that Pharmacia is a Delaware corporation with its principal
15 place of business in New Jersey. Defendants admit that Pharmacia acquired Searle in 2000 and
16 that, as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer.
17 Defendants admit that, during certain periods of time, Pharmacia marketed and co-promoted
18 Celebrex® in the United States to be prescribed by healthcare providers who are by law
19 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny
20 the remaining allegations in this paragraph of the Complaint.

21 7. Defendants admit that in 1933 an entity known as Monsanto Company ("1933
22 Monsanto") was incorporated under the laws of Delaware. On March 31, 2000, a subsidiary of
23 1933 Monsanto merged with Pharmacia & Upjohn, Inc, and 1933 Monsanto changed its name to
24 Pharmacia Corporation. On February 9, 2000, a separate company, Monsanto Ag Company, was
25 incorporated under the laws of Delaware. On March 31, 2000, Monsanto Ag Company changed
26 its name to Monsanto Company ("2000 Monsanto"). The 2000 Monsanto is engaged in the
27 agricultural business and does not and has not ever manufactured, marketed, sold, or distributed
28 Celebrex®. The 2000 Monsanto is not and has never been the parent of either Searle or

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1 Pharmacia. As the 2000 Monsanto does not and has not ever manufactured, marketed, sold, or
2 distributed Celebrex®, Defendants therefore state that the 2000 Monsanto is not a proper party in
3 this matter. Defendants deny the remaining allegations in this paragraph of the Complaint.
4 Defendants state that the response to this paragraph of the Complaint regarding Monsanto is
5 incorporated by reference into Defendants' responses to each and every paragraph of the
6 Complaint referring to Monsanto and/or Defendants.

7 8. Defendants admit that, during certain periods of time, Pfizer and Pharmacia
8 marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare
9 providers who are by law authorized to prescribe drugs in accordance with their approval by the
10 FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and
11 packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex®
12 in the United States to be prescribed by healthcare providers who are by law authorized to
13 prescribe drugs in accordance with their approval by the FDA. Defendants admit that Pharmacia
14 acquired Searle in 2000 and that, as the result of a merger in April 2003, Searle and Pharmacia
15 became subsidiaries of Pfizer. Defendants deny the remaining allegations in this paragraph of
16 the Complaint.

17 9. Defendants admit that, during certain periods of time, Pfizer and Pharmacia
18 marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare
19 providers who are by law authorized to prescribe drugs in accordance with their approval by the
20 FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and
21 packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex®
22 in the United States to be prescribed by healthcare providers who are by law authorized to
23 prescribe drugs in accordance with their approval by the FDA. Defendants state that Celebrex®
24 was and is safe and effective when used in accordance with its FDA-approved prescribing
25 information. Defendants state that the potential effects of Celebrex® were and are adequately
26 described in its FDA-approved prescribing information, which was at all times adequate and
27 comported with applicable standards of care and law. Defendants deny any wrongful conduct
28 and deny the remaining allegations in this paragraph of the Complaint.

10. Defendants state that the allegations in this paragraph of the Complaint regarding “predecessors in interest” are vague and ambiguous. Defendants are without knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

Response to Factual Allegations

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1 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
2 Celebrex® caused Plaintiff injury or damages, and deny the remaining allegations in this
3 paragraph of the Complaint.

4 15. Defendants are without knowledge or information sufficient to form a belief as to
5 the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
6 Celebrex®, and, therefore, deny the same. Defendants state that, in the ordinary case,
7 Celebrex® was expected to reach users and consumers without substantial change from the time
8 of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

9 16. Defendants are without knowledge or information sufficient to form a belief as to
10 the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
11 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
12 effective when used in accordance with its FDA-approved prescribing information. Defendants
13 state that the potential effects of Celebrex® were and are adequately described in its FDA-
14 approved prescribing information, which was at all times adequate and comported with
15 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
16 remaining allegations in this paragraph of the Complaint.

17 17. Defendants state that the allegations in this paragraph of the Complaint regarding
18 aspirin, naproxen, and ibuprofen are not directed toward Defendants, and, therefore, no response
19 is required. Defendants admit that Celebrex® is in a class of drugs that are, at times, referred to
20 as being a non-steroidal anti-inflammatory (“NSAID”) drugs. Defendants deny the remaining
21 allegations in this paragraph of the Complaint.

22 18. Defendants state that the allegations in this paragraph of the Complaint are not
23 directed toward Defendants and, therefore, no response is required. To the extent that a response
24 is deemed required, Defendants state that Plaintiff fails to provide the proper context for the
25 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information
26 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

27 19. Defendants state that the allegations in this paragraph of the Complaint are not
28 directed toward Defendants and, therefore, no response is required. To the extent that a response

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1 is deemed required, Defendants state that Plaintiff fails to provide the proper context for the
2 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information
3 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

4 20. Defendants state that the allegations in this paragraph of the Complaint are not
5 directed toward Defendants and, therefore, no response is required. To the extent that a response
6 is deemed required, Defendants state that Plaintiff fails to provide the proper context for the
7 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information
8 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

9 21. Defendants state that the allegations in this paragraph of the Complaint are not
10 directed toward Defendants and, therefore, no response is required. To the extent a response is
11 deemed required, Defendants state that, as stated in the FDA-approved labeling for Celebrex®,
12 “[t]he mechanism of action of Celebrex is believed to be due to inhibition of prostaglandin
13 synthesis, primarily via inhibition of cyclooxygenase-2 (COX-2), and at therapeutic
14 concentrations in humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) isoenzyme.”
15 Plaintiff fails to provide the proper context for the remaining allegations in this paragraph and
16 Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of
17 the allegations and, therefore, deny the remaining allegations in this paragraph of the Complaint.

18 22. Defendants state that the allegations in this paragraph of the Complaint regarding
19 “predecessors in interest” are vague and ambiguous. Defendants are without knowledge or
20 information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the
21 same. Defendants state that, as stated in the FDA-approved labeling for Celebrex®, “[t]he
22 mechanism of action of Celebrex is believed to be due to inhibition of prostaglandin synthesis,
23 primarily via inhibition of cyclooxygenase-2 (COX-2), and at therapeutic concentrations in
24 humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) isoenzyme.” Defendants state
25 that Celebrex® was and is safe and effective when used in accordance with its FDA-approved
26 prescribing information. Defendants state that the potential effects of Celebrex® were and are
27 adequately described in its FDA-approved prescribing information, which was at all times
28 adequate and comported with applicable standards of care and law. Defendants deny any

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1 wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

2 23. Defendants admit that Searle submitted a New Drug Application (“NDA”) for
3 Celebrex® on June 29, 1998. Defendants admit that, on December 31, 1998, the FDA granted
4 approval of Celebrex® for the following indications: (1) for relief of the signs and symptoms of
5 osteoarthritis; and (2) for relief of the signs and symptoms of rheumatoid arthritis in adults.
6 Defendants admit that, on December 23, 1999, the FDA granted approval of Celebrex® to
7 reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis (“FAP”)
8 as an adjunct to usual care (e.g., endoscopic surveillance surgery). Defendants deny the
9 remaining allegations in this paragraph of the Complaint.

10 24. Defendants admit that Celebrex® was launched in February 1999. Defendants
11 admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted
12 Celebrex® in the United States to be prescribed by healthcare providers who are by law
13 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit
14 that, during certain periods of time, Celebrex® was manufactured and packaged for Searle,
15 which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States
16 to be prescribed by healthcare providers who are by law authorized to prescribe drugs in
17 accordance with their approval by the FDA. Defendants state that Celebrex® was and is safe
18 and effective when used in accordance with its FDA-approved prescribing information.
19 Defendants state that the potential effects of Celebrex® were and are adequately described in its
20 FDA-approved prescribing information, which was at all times adequate and comported with
21 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
22 remaining allegations in this paragraph of the Complaint.

23 25. Defendants state that the referenced article speaks for itself and respectfully refer
24 the Court to the article for its actual language and text. Any attempt to characterize the article is
25 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

26 26. Defendants state that the referenced article speaks for itself and respectfully refer
27 the Court to the article for its actual language and text. Any attempt to characterize the article is
28 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

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1 27. Defendants state that the referenced FDA Update speaks for itself and respectfully
2 refer the Court to the FDA Update for its actual language and text. Any attempt to characterize
3 the FDA Update is denied. Defendants deny the remaining allegations in this paragraph of the
4 Complaint.

5 28. Defendants state that Celebrex® was and is safe and effective when used in
6 accordance with its FDA-approved prescribing information. Defendants state that the potential
7 effects of Celebrex® were and are adequately described in its FDA-approved prescribing
8 information, which was at all times adequate and comported with applicable standards of care
9 and law. Defendants deny the allegations in this paragraph of the Complaint.

10 29. Defendants state that Celebrex® was and is safe and effective when used in
11 accordance with its FDA-approved prescribing information. Defendants state that the potential
12 effects of Celebrex® were and are adequately described in its FDA-approved prescribing
13 information, which was at all times adequate and comported with applicable standards of care
14 and law. Defendants deny any wrongful conduct and deny the remaining allegations in this
15 paragraph of the Complaint.

16 30. Defendants admit that a supplemental NDA for Celebrex® was submitted to the
17 FDA on June 12, 2000. Defendants assert that the submission speaks for itself and any attempt
18 to characterize it is denied. Defendants admit that a Medical Officer Review dated September
19 20, 2000, was completed by the FDA. Defendants state that the referenced study speaks for
20 itself and respectfully refer the Court to the study for its actual language and text. Any attempt
21 to characterize the study is denied. Defendants deny the remaining allegations in this paragraph
22 of the Complaint.

23 31. Defendants state that the referenced article speaks for itself and respectfully refer
24 the Court to the article for its actual language and text. Any attempt to characterize the article is
25 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

26 32. Defendants state that the referenced study speaks for itself and respectfully refer
27 the Court to the study for its actual language and text. Any attempt to characterize the study is
28 denied. Defendants deny any wrongful conduct and deny the remaining allegations in this

1 paragraph of the Complaint.

2 33. Defendants state that the referenced Medical Officer Review speaks for itself and
3 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any
4 attempt to characterize the Medical Officer Review is denied. Defendants state that the
5 referenced study speaks for itself and respectfully refer the Court to the study for its actual
6 language and text. Any attempt to characterize the study is denied. Defendants deny the
7 remaining allegations in this paragraph of the Complaint.

8 34. Defendants state that the transcripts of the FDA Arthritis Drugs Advisory
9 Committee hearings speak for themselves and respectfully refer the Court to the transcripts for
10 their actual language and text. Any attempt to characterize the transcripts is denied. Defendants
11 state that the referenced study speaks for itself and respectfully refer the Court to the study for its
12 actual language and text. Any attempt to characterize the study is denied. Defendants deny the
13 remaining allegations in this paragraph of the Complaint.

14 35. Defendants state that the referenced articles speak for themselves and respectfully
15 refer the Court to the articles for their actual language and text. Any attempt to characterize the
16 articles is denied. Defendants state that the referenced study speaks for itself and respectfully
17 refer the Court to the study for its actual language and text. Any attempt to characterize the
18 study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

19 36. Defendants state that the referenced article speaks for itself and respectfully refer
20 the Court to the article for its actual language and text. Any attempt to characterize the article is
21 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

22 37. Defendants state that the referenced articles speak for themselves and respectfully
23 refer the Court to the articles for their actual language and text. Any attempt to characterize the
24 articles is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

25 38. Defendants state that the referenced article speaks for itself and respectfully refer
26 the Court to the article for its actual language and text. Any attempt to characterize the article is
27 denied. Defendants state that the referenced study speaks for itself and respectfully refer the
28 Court to the study for its actual language and text. Any attempt to characterize the study is

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1 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

2 39. Defendants state that the referenced Medical Officer Review speaks for itself and
3 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any
4 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining
5 allegations in this paragraph of the Complaint.

6 40. Plaintiff fails to provide the proper context for the allegations concerning “Public
7 Citizen” in this paragraph of the Complaint. Defendants therefore lack sufficient information or
8 knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.
9 Defendants deny the remaining allegations in this paragraph of the Complaint.

10 41. Defendants state that the referenced article speaks for itself and respectfully refer
11 the Court to the article for its actual language and text. Any attempt to characterize the article is
12 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

13 42. Defendants state that the referenced study speaks for itself and respectfully refer
14 the Court to the study for its actual language and text. Any attempt to characterize the study is
15 denied. Plaintiff fails to provide the proper context for the allegations concerning “Public
16 Citizen” in this paragraph of the Complaint. Defendants therefore lack sufficient information or
17 knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.
18 Defendants deny the remaining allegations in this paragraph of the Complaint.

19 43. Defendants admit that there was a clinical trial called APC. Defendants state that
20 the referenced article speaks for itself and respectfully refer the Court to the article for its actual
21 language and text. Any attempt to characterize the article is denied. Defendants deny the
22 remaining allegations in this paragraph of the Complaint.

23 44. Defendants state that the referenced article speaks for itself and respectfully refer
24 the Court to the article for its actual language and text. Any attempt to characterize the article is
25 denied. Plaintiff fails to provide the proper context for the allegations concerning “Data Safety
26 Monitoring Board” in this paragraph of the Complaint. Defendants therefore lack sufficient
27 information or knowledge to form a belief as to the truth of such allegations and, therefore, deny
28 the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

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1 45. Defendants state that the referenced article speaks for itself and respectfully refer
2 the Court to the article for its actual language and text. Any attempt to characterize the article is
3 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

4 46. Defendants state that the referenced Alert for Healthcare Professionals speaks for
5 itself and respectfully refer the Court to the Alert for Healthcare Professionals for its actual
6 language and text. Any attempt to characterize the Alert for Healthcare Professionals is denied.
7 Defendants deny the remaining allegations in this paragraph of the Complaint.

8 47. Defendants state that the referenced Medical Officer Review speaks for itself and
9 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any
10 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining
11 allegations in this paragraph of the Complaint.

12 48. Defendants admit that there was a clinical trial called PreSAP. Plaintiff fails to
13 provide the proper context for the allegations concerning “other Celebrex trials” contained in this
14 paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to
15 form a belief as to the truth of such allegations and, therefore, deny the same. As for the
16 allegations in this paragraph of the Complaint regarding the PreSAP study, Defendants state that
17 the referenced study speaks for itself and respectfully refer the Court to the study for its actual
18 language and text. Any attempt to characterize the study is denied. Defendants deny the
19 remaining allegations in this paragraph of the Complaint.

20 49. Defendants state that the referenced article speaks for itself and respectfully refer
21 the Court to the article for its actual language and text. Any attempt to characterize the article is
22 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

23 50. Plaintiff fails to provide the proper context for the allegations regarding Merck
24 and Vioxx® in this paragraph of the Complaint. Defendants therefore lack sufficient
25 information or knowledge to form a belief as to the truth of such allegations and, therefore, deny
26 the same. Defendants state that the referenced studies speak for themselves and respectfully
27 refer the Court to the studies for their actual language and text. Any attempt to characterize the
28 studies is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

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1 51. Defendants state that the referenced Medical Officer Review speaks for itself and
2 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any
3 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining
4 allegations in this paragraph of the Complaint.

5 52. Defendants state that allegations regarding Vioxx® in this paragraph of the
6 Complaint are not directed toward Defendants, and therefore no response is required. To the
7 extent that a response is deemed required, Plaintiff fails to provide the proper context for the
8 allegations regarding Vioxx® in this paragraph of the Complaint. Defendants therefore lack
9 sufficient information or knowledge to form a belief as to the truth of such allegations and,
10 therefore, deny the same. Defendants state that the referenced study speaks for itself and
11 respectfully refer the Court to the study for its actual language and text. Any attempt to
12 characterize the study is denied. Defendants deny the remaining allegations in this paragraph of
13 the Complaint.

14 53. Defendants state that allegations regarding Merck and Vioxx® in this paragraph
15 of the Complaint are not directed toward Defendants, and therefore no response is required. To
16 the extent that a response is deemed required, Plaintiff fails to provide the proper context for the
17 allegations regarding Merck and Vioxx® in this paragraph of the Complaint. Defendants
18 therefore lack sufficient information or knowledge to form a belief as to the truth of such
19 allegations and, therefore, deny the same. Defendants state that the referenced study speaks for
20 itself and respectfully refer the Court to the study for its actual language and text. Any attempt
21 to characterize the study is denied. Defendants deny the remaining allegations in this paragraph
22 of the Complaint.

23 54. Defendants state that allegations regarding Merck and Vioxx® in this paragraph
24 of the Complaint are not directed toward Defendants, and therefore no response is required. To
25 the extent that a response is deemed required, Plaintiff fails to provide the proper context for the
26 allegations regarding Merck and Vioxx® in this paragraph of the Complaint. Defendants
27 therefore lack sufficient information or knowledge to form a belief as to the truth of such
28 allegations and, therefore, deny the same. Defendants state that the referenced study speaks for

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1 itself and respectfully refer the Court to the study for its actual language and text. Any attempt
2 to characterize the study is denied. Defendants state that the referenced article speaks for itself
3 and respectfully refer the Court to the article for its actual language and text. Any attempt to
4 characterize the article is denied. Defendants deny the remaining allegations in this paragraph of
5 the Complaint.

6 55. Defendants state that Celebrex® was and is safe and effective when used in
7 accordance with its FDA-approved prescribing information. Defendants deny the allegations in
8 this paragraph of the Complaint.

9 56. Defendants state that the referenced article speaks for itself and respectfully refer
10 the Court to the article for its actual language and text. Any attempt to characterize the article is
11 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

12 57. Defendants state that allegations in this paragraph of the Complaint are not
13 directed toward Defendants, and therefore no response is required. To the extent that a response
14 is deemed required, Defendants state that the referenced article speaks for itself and respectfully
15 refer the Court to the article for its actual language and text. Any attempt to characterize the
16 article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

17 58. Defendants deny the allegations in this paragraph of the Complaint.

18 59. Defendants state that Celebrex® was and is safe and effective when used in
19 accordance with its FDA-approved prescribing information. Defendants state that the potential
20 effects of Celebrex® were and are adequately described in its FDA-approved prescribing
21 information, which was at all times adequate and comported with applicable standards of care
22 and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the
23 remaining allegations contained in this paragraph of the Complaint.

24 60. Defendants deny any wrongful conduct and deny the remaining allegations
25 contained in this paragraph of the Complaint.

26 61. Defendants deny any wrongful conduct and deny the remaining allegations
27 contained in this paragraph of the Complaint.

28 62. Defendants state that Celebrex® was and is safe and effective when used in

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1 accordance with its FDA-approved prescribing information. Defendants state that the potential
2 effects of Celebrex® were and are adequately described in its FDA-approved prescribing
3 information, which was at all times adequate and comported with applicable standards of care
4 and law. Defendants deny any wrongful conduct and deny the remaining allegations contained
5 in this paragraph of the Complaint.

6 63. Defendants are without knowledge or information sufficient to form a belief as to
7 the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
8 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
9 effective when used in accordance with its FDA-approved prescribing information. Defendants
10 state that the potential effects of Celebrex® were and are adequately described in its FDA-
11 approved prescribing information, which was at all times adequate and comported with
12 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
13 Celebrex® is unreasonably dangerous, and deny the remaining allegations in this paragraph of
14 the Complaint.

15 64. Defendants admit that the FDA Division of Drug Marketing, Advertising, and
16 Communications (“DDMAC”) sent letters to Searle dated October 6, 1999, April 6, 2000, and
17 November 14, 2000. Defendants state that the referenced letters speak for themselves and
18 respectfully refer the Court to the letters for their actual language and text. Any attempt to
19 characterize the letters is denied. Defendants deny the remaining allegations in this paragraph of
20 the Complaint.

21 65. Defendants admit that the DDMAC sent a letter to Pharmacia dated February 1,
22 2001. Defendants state that the referenced letter speaks for itself and respectfully refer the Court
23 to the letter for its actual language and text. Any attempt to characterize the letter is denied.
24 Defendants deny the remaining allegations in this paragraph of the Complaint.

25 66. Defendants state that the referenced article speaks for itself and respectfully refer
26 the Court to the article for its actual language and text. Any attempt to characterize the article is
27 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

28 67. Defendants admit that the DDMAC sent a letter to Pfizer dated January 10, 2005.

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1 Defendants state that the referenced letter speaks for itself and respectfully refer the Court to the
2 letter for its actual language and text. Any attempt to characterize the letter is denied.

3 Defendants deny the remaining allegations in this paragraph of the Complaint.

4 68. Defendants state that Celebrex® was and is safe and effective when used in
5 accordance with its FDA-approved prescribing information. Defendants state that the potential
6 effects of Celebrex® were and are adequately described in its FDA-approved prescribing
7 information, which was at all times adequate and comported with applicable standards of care
8 and law. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
9 and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who
10 are by law authorized to prescribe drugs in accordance with their approval by the FDA.
11 Defendants admit that, during certain periods of time, Celebrex® was manufactured and
12 packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex®
13 in the United States to be prescribed by healthcare providers who are by law authorized to
14 prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining
15 allegations in this paragraph of the Complaint.

16 69. Defendants state that Celebrex® was and is safe and effective when used in
17 accordance with its FDA-approved prescribing information. Defendants state that the potential
18 effects of Celebrex® were and are adequately described in its FDA-approved prescribing
19 information, which was at all times adequate and comported with applicable standards of care
20 and law. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
21 and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who
22 are by law authorized to prescribe drugs in accordance with their approval by the FDA.
23 Defendants admit that, during certain periods of time, Celebrex® was manufactured and
24 packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex®
25 in the United States to be prescribed by healthcare providers who are by law authorized to
26 prescribe drugs in accordance with their approval by the FDA. Defendants state that Celebrex®
27 is a prescription medication which is approved by the FDA for the following indications: (1) for
28 relief of the signs and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of

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1 rheumatoid arthritis in adults; (3) for the management of acute pain in adults; (4) for the
2 treatment of primary dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps
3 in familial adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic
4 surveillance surgery); (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for
5 relief of the signs and symptoms of juvenile rheumatoid arthritis in patients two years of age and
6 older. Defendants deny any wrongful conduct and deny the remaining allegations in this
7 paragraph of the Complaint.

8 70. Defendants state that Celebrex® was and is safe and effective when used in
9 accordance with its FDA-approved prescribing information. Defendants state that the potential
10 effects of Celebrex® were and are adequately described in its FDA-approved prescribing
11 information, which at all times was adequate and comported with applicable standards of care
12 and law. Defendants state that Plaintiff's allegations regarding "predecessors in interest" are
13 vague and ambiguous. Defendants are without knowledge or information to form a belief as to
14 the truth of such allegations, and, therefore, deny the same. Defendants deny any wrongful
15 conduct, deny that Celebrex® is defective, and deny the remaining allegations in this paragraph
16 of the Complaint.

17 71. Defendants state that Celebrex® was and is safe and effective when used in
18 accordance with its FDA-approved prescribing information. Defendants state that the potential
19 effects of Celebrex® were and are adequately described in its FDA-approved prescribing
20 information, which was at all times adequate and comported with applicable standards of care
21 and law. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
22 and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who
23 are by law authorized to prescribe drugs in accordance with their approval by the FDA.
24 Defendants admit that, during certain periods of time, Celebrex® was manufactured and
25 packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex®
26 in the United States to be prescribed by healthcare providers who are by law authorized to
27 prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining
28 allegations in this paragraph of the Complaint.

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72. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

73. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

74. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

75. Defendants deny the allegations in this paragraph of the Complaint.

76. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing

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1 information, which was at all times adequate and comported with applicable standards of care
2 and law. Defendants deny any wrongful conduct and deny the remaining allegations in this
3 paragraph of the Complaint.

4 77. Defendants state that Celebrex® was and is safe and effective when used in
5 accordance with its FDA-approved prescribing information. Defendants state that the potential
6 effects of Celebrex® were and are adequately described in its FDA-approved prescribing
7 information, which was at all times adequate and comported with applicable standards of care
8 and law. Defendants deny any wrongful conduct and deny the remaining allegations in this
9 paragraph of the Complaint.

10 78. Defendants are without knowledge or information sufficient to form a belief as to
11 the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
12 Celebrex®, and, therefore, deny the same. Defendants deny any wrongful conduct, deny that
13 Celebrex® caused Plaintiff injury or damages, and deny the remaining allegations in this
14 paragraph of the Complaint.

15 79. Defendants state that Celebrex® was and is safe and effective when used in
16 accordance with its FDA-approved prescribing information. Defendants state that the potential
17 effects of Celebrex® were and are adequately described in its FDA-approved prescribing
18 information, which was at all times adequate and comported with applicable standards of care
19 and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the
20 remaining allegations in this paragraph of the Complaint.

21 80. Defendants state that Celebrex® was and is safe and effective when used in
22 accordance with its FDA-approved prescribing information. Defendants state that the potential
23 effects of Celebrex® are and were adequately described in its FDA-approved prescribing
24 information, which was at all times adequate and comported with applicable standards of care
25 and law. Defendants deny any wrongful conduct and deny the remaining allegations in this
26 paragraph of the Complaint.

27 81. Defendants state that Celebrex® was and is safe and effective when used in
28 accordance with its FDA-approved prescribing information. Defendants state that the potential

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1 effects of Celebrex® are and were adequately described in its FDA-approved prescribing
2 information, which was at all times adequate and comported with applicable standards of care
3 and law. Defendants state that the referenced study speaks for itself and respectfully refer the
4 Court to the study for its actual language and text. Any attempt to characterize the study is
5 denied. Defendants deny any wrongful conduct and deny the remaining allegations in this
6 paragraph of the Complaint.

7 82. Defendants deny any wrongful conduct and deny the remaining allegations in this
8 paragraph of the Complaint.

9 83. Defendants are without knowledge or information sufficient to form a belief as to
10 the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
11 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
12 effective when used in accordance with its FDA-approved prescribing information. Defendants
13 state that the potential effects of Celebrex® are and were adequately described in its FDA-
14 approved prescribing information, which was at all times adequate and comported with
15 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
16 remaining allegations in this paragraph of the Complaint.

17 Response to First Cause of Action: Negligence

18 84. Defendants incorporate by reference their responses to each paragraph of
19 Plaintiff's Complaint as if fully set forth herein.

20 85. Defendants state that this paragraph of the Complaint contains legal contentions
21 to which no response is required. To the extent that a response is deemed required, Defendants
22 admit that they had duties as are imposed by law but deny having breached such duties.
23 Defendants state that Celebrex® was and is safe and effective when used in accordance with its
24 FDA-approved prescribing information. Defendants state that the potential effects of Celebrex®
25 were and are adequately described in its FDA-approved prescribing information, which was at all
26 times adequate and comported with applicable standards of care and law. Defendants deny any
27 wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

28 86. Defendants state that this paragraph of the Complaint contains legal contentions

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1 to which no response is required. To the extent that a response is deemed required, Defendants
2 admit that they had duties as are imposed by law but denies having breached such duties.
3 Defendants state that Celebrex® was and is safe and effective when used in accordance with its
4 FDA-approved prescribing information. Defendants state that the potential effects of Celebrex®
5 were and are adequately described in its FDA-approved prescribing information, which was at all
6 times adequate and comported with applicable standards of care and law. Defendants deny any
7 wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

8 87. Defendants state that this paragraph of the Complaint contains legal contentions
9 to which no response is required. To the extent that a response is deemed required, Defendants
10 admit that they had duties as are imposed by law but deny having breached such duties.
11 Defendants are without knowledge or information sufficient to form a belief as to the truth of the
12 allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and,
13 therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when
14 used in accordance with its FDA-approved prescribing information. Defendants state that the
15 potential effects of Celebrex® were and are adequately described in its FDA-approved
16 prescribing information, which was at all times adequate and comported with applicable
17 standards of care and law. Defendants deny any wrongful conduct and deny the remaining
18 allegations in this paragraph of the Complaint, including all subparts.

19 88. Defendants are without knowledge or information sufficient to form a belief as to
20 the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
21 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
22 effective when used in accordance with its FDA-approved prescribing information. Defendants
23 state that the potential effects of Celebrex® were and are adequately described in its FDA-
24 approved prescribing information, which was at all times adequate and comported with
25 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
26 remaining allegations in this paragraph of the Complaint.

27 89. Defendants state that Celebrex® was and is safe and effective when used in
28 accordance with its FDA-approved prescribing information. Defendants state that the potential

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1 effects of Celebrex® were and are adequately described in its FDA-approved prescribing
2 information, which was at all times adequate and comported with applicable standards of care
3 and law. Defendants deny any wrongful conduct and deny the remaining allegations in this
4 paragraph of the Complaint.

5 90. Defendants are without knowledge or information sufficient to form a belief as to
6 the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
7 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
8 effective when used in accordance with its FDA-approved prescribing information. Defendants
9 state that the potential effects of Celebrex® were and are adequately described in its FDA-
10 approved prescribing information, which was at all times adequate and comported with
11 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
12 remaining allegations in this paragraph of the Complaint.

13 91. Defendants are without knowledge or information sufficient to form a belief as to
14 the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's medical
15 condition or whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants deny
16 any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damages, and deny the
17 remaining allegations in this paragraph of the Complaint.

18 92. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff
19 injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

20 Answering the unnumbered paragraph following Paragraph 92 of the Complaint,
21 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damages,
22 and deny the remaining allegations in this paragraph of the Complaint.

23 Response to Second Cause of Action: Strict Liability

24 93. Defendants incorporate by reference their responses to each paragraph of
25 Plaintiff's Complaint as if fully set forth herein.

26 94. Defendants are without knowledge or information sufficient to form a belief as to
27 the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
28 Celebrex®, and, therefore, deny the same. Defendants admit that, during certain periods of time,

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1 Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed
2 by healthcare providers who are by law authorized to prescribe drugs in accordance with their
3 approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was
4 manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and
5 distributed Celebrex® in the United States to be prescribed by healthcare providers who are by
6 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
7 state that, in the ordinary case, Celebrex® was expected to reach users and consumers without
8 substantial change from the time of sale. Defendants deny the remaining allegations in this
9 paragraph of the Complaint.

10 95. Defendants state that Celebrex® was and is safe and effective when used in
11 accordance with its FDA-approved prescribing information. Defendants state that the potential
12 effects of Celebrex® were and are adequately described in its FDA-approved prescribing
13 information, which was at all times adequate and comported with applicable standards of care
14 and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

15 96. Defendants state that Celebrex® was and is safe and effective when used in
16 accordance with its FDA-approved prescribing information. Defendants state that the potential
17 effects of Celebrex® were and are adequately described in its FDA-approved prescribing
18 information, which was at all times adequate and comported with applicable standards of care
19 and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective or
20 unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

21 97. Defendants state that Celebrex® was and is safe and effective when used in
22 accordance with its FDA-approved prescribing information. Defendants state that the potential
23 effects of Celebrex® were and are adequately described in its FDA-approved prescribing
24 information, which was at all times adequate and comported with applicable standards of care
25 and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective or
26 unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

27 98. Defendants state that Celebrex® was and is safe and effective when used in
28 accordance with its FDA-approved prescribing information. Defendants state that the potential

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1 effects of Celebrex® were and are adequately described in its FDA-approved prescribing
2 information, which was at all times adequate and comported with applicable standards of care
3 and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the
4 remaining allegations in this paragraph of the Complaint.

5 99. Defendants state that Celebrex® was and is safe and effective when used in
6 accordance with its FDA-approved prescribing information. Defendants state that the potential
7 effects of Celebrex® were and are adequately described in its FDA-approved prescribing
8 information, which was at all times adequate and comported with applicable standards of care
9 and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the
10 remaining allegations in this paragraph of the Complaint.

11 100. Defendants are without knowledge or information sufficient to form a belief as to
12 the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
13 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
14 effective when used in accordance with its FDA-approved prescribing information. Defendants
15 state that the potential effects of Celebrex® were and are adequately described in its FDA-
16 approved prescribing information, which was at all times adequate and comported with
17 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
18 Celebrex® is defective, deny that Celebrex® caused Plaintiff injury or damages, and deny the
19 remaining allegations in this paragraph of the Complaint.

20 101. Defendants state that Celebrex® was and is safe and effective when used in
21 accordance with its FDA-approved prescribing information. Defendants state that the potential
22 effects of Celebrex® were and are adequately described in its FDA-approved prescribing
23 information, which was at all times adequate and comported with applicable standards of care
24 and law. Defendants deny any wrongful conduct and deny the remaining allegations in this
25 paragraph of the Complaint.

26 102. Defendants are without knowledge or information sufficient to form a belief as to
27 the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
28 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and

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1 effective when used in accordance with its FDA-approved prescribing information. Defendants
2 state that the potential effects of Celebrex® were and are adequately described in its FDA-
3 approved prescribing information, which was at all times adequate and comported with
4 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
5 Celebrex® caused Plaintiff injury or damages, and deny the remaining allegations in this
6 paragraph of the Complaint.

7 103. Defendants state that Celebrex® was and is safe and effective when used in
8 accordance with its FDA-approved prescribing information. Defendants state that the potential
9 effects of Celebrex® were and are adequately described in its FDA-approved prescribing
10 information, which was at all times adequate and comported with applicable standards of care
11 and law. Defendants deny any wrongful conduct and deny the remaining allegations in this
12 paragraph of the Complaint.

13 104. Defendants are without knowledge or information sufficient to form a belief as to
14 the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
15 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
16 effective when used in accordance with its FDA-approved prescribing information. Defendants
17 state that the potential effects of Celebrex® were and are adequately described in its FDA-
18 approved prescribing information, which was at all times adequate and comported with
19 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
20 remaining allegations in this paragraph of the Complaint

21 105. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff
22 injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

23 106. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff
24 injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

25 107. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff
26 injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

27 Response to Third Cause of Action: Breach of Express Warranty

28 108. Defendants incorporate by reference their responses to each paragraph of

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1 Plaintiff's Complaint as if fully set forth herein.

2 109. Defendants are without knowledge or information sufficient to form a belief as to
3 the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
4 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
5 effective when used in accordance with its FDA-approved prescribing information. Defendants
6 state that the potential effects of Celebrex® were and are adequately described in its FDA-
7 approved prescribing information, which was at all times adequate and comported with
8 applicable standards of care and law. Defendants admit to providing FDA-approved prescribing
9 information for Celebrex®. Defendants deny the remaining allegations in this paragraph of the
10 Complaint.

11 110. Defendants are without knowledge or information sufficient to form a belief as to
12 the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
13 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
14 effective when used in accordance with its FDA-approved prescribing information. Defendants
15 state that the potential effects of Celebrex® were and are adequately described in its FDA-
16 approved prescribing information, which was at all times adequate and comported with
17 applicable standards of care and law. Defendants admit to providing FDA-approved prescribing
18 information for Celebrex®. Defendants deny any wrongful conduct and deny the remaining
19 allegations in this paragraph of the Complaint, including all subparts.

20 111. Defendants admit to providing FDA-approved prescribing information for
21 Celebrex®. Defendants deny any wrongful conduct and deny the remaining allegations in this
22 paragraph of the Complaint.

23 112. Defendants state that Celebrex® was and is safe and effective when used in
24 accordance with its FDA-approved prescribing information. Defendants state that the potential
25 effects of Celebrex® were and are adequately described in its FDA-approved prescribing
26 information, which was at all times adequate and comported with applicable standards of care
27 and law. Defendants deny any wrongful conduct and deny the remaining allegations in this
28 paragraph of the Complaint.

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1 113. Defendants state that Celebrex® was and is safe and effective when used in
2 accordance with its FDA-approved prescribing information. Defendants state that the potential
3 effects of Celebrex® were and are adequately described in its FDA-approved prescribing
4 information, which was at all times adequate and comported with applicable standards of care
5 and law. Defendants deny any wrongful conduct and deny the remaining allegations in this
6 paragraph of the Complaint.

7 114. Defendants are without knowledge or information sufficient to form a belief as to
8 the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
9 Celebrex®, and, therefore, deny the same. Defendants state that the potential effects of
10 Celebrex® were and are adequately described in its FDA-approved prescribing information,
11 which was at all times adequate and comported with applicable standards of care and law.
12 Defendants admit to providing FDA-approved prescribing information for Celebrex®.
13 Defendants deny the remaining allegations in this paragraph of the Complaint.

14 115. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff
15 injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

16 116. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff
17 injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

18 117. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff
19 injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

20 Response to Fourth Cause of Action: Breach of Implied Warranty

21 118. Defendants incorporate by reference their responses to each paragraph of
22 Plaintiff's Complaint as if fully set forth herein.

23 119. Defendants admit that, during certain periods of time, Pfizer and Pharmacia
24 marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare
25 providers who are by law authorized to prescribe drugs in accordance with their approval by the
26 FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and
27 packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex®
28 in the United States to be prescribed by healthcare providers who are by law authorized to

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1 prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining
2 allegations in this paragraph of the Complaint.

3 120. Defendants state that Celebrex® was and is safe and effective when used in
4 accordance with its FDA-approved prescribing information. Defendants state that the potential
5 effects of Celebrex® were and are adequately described in its FDA-approved prescribing
6 information, which was at all times adequate and comported with applicable standards of care
7 and law. Defendants admit to providing FDA-approved prescribing information for Celebrex®.
8 Defendants deny the remaining allegations in this paragraph of the Complaint.

9 121. Defendants state that Celebrex® was and is safe and effective when used in
10 accordance with its FDA-approved prescribing information. Defendants state that the potential
11 effects of Celebrex® were and are adequately described in its FDA-approved prescribing
12 information, which was at all times adequate and comported with applicable standards of care
13 and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

14 122. Defendants state that this paragraph of the Complaint contains legal contentions
15 to which no response is required. To the extent that a response is deemed required, Defendants
16 state that Celebrex® was and is safe and effective when used in accordance with its FDA-
17 approved prescribing information. Defendants state that the potential effects of Celebrex® were
18 and are adequately described in its FDA-approved prescribing information, which was at all
19 times adequate and comported with applicable standards of care and law. Defendants deny any
20 wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

21 123. Defendants are without knowledge or information sufficient to form a belief as to
22 the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
23 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® is a prescription
24 medication which is approved by the FDA for the following indications: (1) for relief of the signs
25 and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of rheumatoid arthritis
26 in adults; (3) for the management of acute pain in adults; (4) for the treatment of primary
27 dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps in familial
28 adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic surveillance surgery);

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1 (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for relief of the signs and
2 symptoms of juvenile rheumatoid arthritis in patients two years of age and older. Defendants
3 deny the remaining allegations in this paragraph of the Complaint.

4 124. Defendants are without knowledge or information sufficient to form a belief as to
5 the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
6 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
7 effective when used in accordance with its FDA-approved prescribing information. Defendants
8 state that the potential effects of Celebrex® were and are adequately described in its FDA-
9 approved prescribing information, which was at all times adequate and comported with
10 applicable standards of care and law. Defendants admit to providing FDA-approved prescribing
11 information for Celebrex®. Defendants deny the remaining allegations in this paragraph of the
12 Complaint.

13 125. Defendants are without knowledge or information sufficient to form a belief as to
14 the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
15 Celebrex®, and, therefore, deny the same. Defendants state that, in the ordinary case,
16 Celebrex® was expected to reach users and consumers without substantial change from the time
17 of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

18 126. Defendants are without knowledge or information sufficient to form a belief as to
19 the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
20 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
21 effective when used in accordance with its FDA-approved prescribing information. Defendants
22 state that the potential effects of Celebrex® were and are adequately described in its FDA-
23 approved prescribing information, which was at all times adequate and comported with
24 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
25 remaining allegations in this paragraph of the Complaint.

26 127. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff
27 injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

28 128. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff

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1 injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

2 129. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff
3 injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

4 Response to Fifth Cause of Action: Fraudulent Misrepresentation and Concealment

5 130. Defendants incorporate by reference their responses to each paragraph of
6 Plaintiff's Complaint as if fully set forth herein.

7 131. Defendants state that this paragraph of the Complaint contains legal contentions
8 to which no response is required. To the extent that a response is deemed required, Defendants
9 admit that they had duties as are imposed by law but deny having breached such duties.
10 Defendants state that Celebrex® was and is safe and effective when used in accordance with its
11 FDA-approved prescribing information. Defendants state that the potential effects of Celebrex®
12 were and are adequately described in its FDA-approved prescribing information, which was at all
13 times adequate and comported with applicable standards of care and law. Defendants deny any
14 wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

15 132. Defendants state that Celebrex® was and is safe and effective when used in
16 accordance with its FDA-approved prescribing information. Defendants state that the potential
17 effects of Celebrex® were and are adequately described in its FDA-approved prescribing
18 information, which was at all times adequate and comported with applicable standards of care
19 and law. Defendants deny any wrongful conduct and deny the remaining allegations in this
20 paragraph of the Complaint, including all subparts.

21 133. Defendants state that Celebrex® was and is safe and effective when used in
22 accordance with its FDA-approved prescribing information. Defendants state that the potential
23 effects of Celebrex® were and are adequately described in its FDA-approved prescribing
24 information, which was at all times adequate and comported with applicable standards of care
25 and law. Defendants deny any wrongful conduct and deny the remaining allegations in this
26 paragraph of the Complaint, including all subparts.

27 134. Defendants are without knowledge or information sufficient to form a belief as to
28 the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used

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1 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
2 effective when used in accordance with its FDA-approved prescribing information. Defendants
3 state that the potential effects of Celebrex® were and are adequately described in its FDA-
4 approved prescribing information, which was at all times adequate and comported with
5 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
6 remaining allegations in this paragraph of the Complaint, including all subparts.

7 135. Defendants state that Celebrex® was and is safe and effective when used in
8 accordance with its FDA-approved prescribing information. Defendants state that the potential
9 effects of Celebrex® were and are adequately described in its FDA-approved prescribing
10 information, which was at all times adequate and comported with applicable standards of care
11 and law. Defendants deny any wrongful conduct and deny the remaining allegations in this
12 paragraph of the Complaint.

13 136. Defendants are without knowledge or information sufficient to form a belief as to
14 the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
15 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
16 effective when used in accordance with its FDA-approved prescribing information. Defendants
17 state that the potential effects of Celebrex® were and are adequately described in its FDA-
18 approved prescribing information, which was at all times adequate and comported with
19 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
20 remaining allegations in this paragraph of the Complaint.

21 137. Defendants are without knowledge or information sufficient to form a belief as to
22 the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
23 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
24 effective when used in accordance with its FDA-approved prescribing information. Defendants
25 state that the potential effects of Celebrex® were and are adequately described in its FDA-
26 approved prescribing information, which was at all times adequate and comported with
27 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
28 remaining allegations in this paragraph of the Complaint.

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1 138. Defendants are without knowledge or information sufficient to form a belief as to
2 the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
3 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
4 effective when used in accordance with its FDA-approved prescribing information. Defendants
5 state that the potential effects of Celebrex® were and are adequately described in its FDA-
6 approved prescribing information, which was at all times adequate and comported with
7 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
8 remaining allegations in this paragraph of the Complaint.

9 139. Defendants are without knowledge or information sufficient to form a belief as to
10 the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
11 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
12 effective when used in accordance with its FDA-approved prescribing information. Defendants
13 state that the potential effects of Celebrex® were and are adequately described in its FDA-
14 approved prescribing information, which was at all times adequate and comported with
15 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
16 remaining allegations in this paragraph of the Complaint.

17 140. Defendants are without knowledge or information sufficient to form a belief as to
18 the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
19 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
20 effective when used in accordance with its FDA-approved prescribing information. Defendants
21 state that the potential effects of Celebrex® were and are adequately described in its FDA-
22 approved prescribing information, which was at all times adequate and comported with
23 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
24 remaining allegations in this paragraph of the Complaint.

25 141. Defendants are without knowledge or information sufficient to form a belief as to
26 the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
27 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
28 effective when used in accordance with its FDA-approved prescribing information. Defendants

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1 state that the potential effects of Celebrex® were and are adequately described in its FDA-
2 approved prescribing information, which was at all times adequate and comported with
3 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
4 remaining allegations in this paragraph of the Complaint.

5 142. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff
6 injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

7 143. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff
8 injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

9 144. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff
10 injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

11 Response to Sixth Cause of Action: Unjust Enrichment

12 145. Defendants incorporate by reference their responses to each paragraph of
13 Plaintiff's Complaint as if fully set forth herein.

14 146. Defendants admit that, during certain periods of time, Pfizer and Pharmacia
15 marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare
16 providers who are by law authorized to prescribe drugs in accordance with their approval by the
17 FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and
18 packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex®
19 in the United States to be prescribed by healthcare providers who are by law authorized to
20 prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining
21 allegations in this paragraph of the Complaint.

22 147. Defendants are without knowledge or information sufficient to form a belief as to
23 the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
24 Celebrex®, and, therefore, deny the same. Defendants deny the remaining allegations in this
25 paragraph of the Complaint.

26 148. Defendants are without knowledge or information sufficient to form a belief as to
27 the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
28 Celebrex®, and, therefore, deny the same. Defendants deny the remaining allegations in this

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1 paragraph of the Complaint.

2 149. Defendants are without knowledge or information sufficient to form a belief as to
3 the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
4 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
5 effective when used in accordance with its FDA-approved prescribing information. Defendants
6 state that the potential effects of Celebrex® were and are adequately described in its FDA-
7 approved prescribing information, which was at all times adequate and comported with
8 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
9 remaining allegations in this paragraph of the Complaint.

10 150. Defendants are without knowledge or information sufficient to form a belief as to
11 the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
12 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
13 effective when used in accordance with its FDA-approved prescribing information. Defendants
14 state that the potential effects of Celebrex® were and are adequately described in its FDA-
15 approved prescribing information, which was at all times adequate and comported with
16 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
17 remaining allegations in this paragraph of the Complaint.

18 151. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff
19 injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

20 Response to Prayer For Relief

21 Answering the unnumbered paragraph of the Complaint headed “Prayer for Relief,”
22 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damages,
23 and deny the remaining allegations this paragraph of the Complaint, including all subparts.

24 III.

25 GENERAL DENIAL

26 Defendants deny the allegations and/or legal conclusions set forth in Plaintiff’s
27 Complaint that have not been previously admitted, denied, or explained.

28 IV.

1 AFFIRMATIVE DEFENSES

2 Defendants reserve the right to rely upon any of the following or additional defenses to
3 claims asserted by Plaintiff to the extent that such defenses are supported by information
4 developed through discovery or evidence at trial. Defendants affirmatively show that:

5 First Defense

6 1. The Complaint fails to state a claim upon which relief can be granted

7 Second Defense

8 2. Celebrex® is a prescription medical product. The federal government has
9 preempted the field of law applicable to the labeling and warning of prescription medical
10 products. Defendants' labeling and warning of Celebrex® was at all times in compliance with
11 applicable federal law. Plaintiff's causes of action against Defendants, therefore, fail to state a
12 claim upon which relief can be granted; such claims, if allowed, would conflict with applicable
13 federal law and violate the Supremacy Clause of the United States Constitution.

14 Third Defense

15 3. At all relevant times, Defendants provided proper warnings, information and
16 instructions for the drug in accordance with generally recognized and prevailing standards in
17 existence at the time.

18 Fourth Defense

19 4. At all relevant times, Defendants' warnings and instructions with respect to the
20 use of Celebrex® conformed to the generally recognized, reasonably available, and reliable state
21 of knowledge at the time the drug was manufactured, marketed and distributed.

22 Fifth Defense

23 5. Plaintiff's action is time-barred as it is filed outside of the time permitted by the
24 applicable Statute of Limitations, and same is pled in full bar of any liability as to Defendants.

25 Sixth Defense

26 6. Plaintiff's action is barred by the statute of repose.

27 Seventh Defense

28 7. If Plaintiff sustained any injuries or incurred any losses or damages as alleged in

1 the Complaint, the same were caused by the negligence or fault of the Plaintiff and Plaintiff's
2 damages, if any, are barred or reduced by the doctrines of comparative fault and contributory
3 negligence and by the failure to mitigate damages.

4 Eighth Defense

5 8. The proximate cause of the loss complained of by Plaintiff is not due to any acts
6 or omissions on the part of Defendants. Rather, said loss is due to the acts or omissions on the
7 part of third parties unrelated to Defendants and for whose acts or omissions Defendants are not
8 liable in any way.

9 Ninth Defense

10 9. The acts and/or omissions of unrelated third parties as alleged constituted
11 independent, intervening causes for which Defendants cannot be liable.

12 Tenth Defense

13 10. Any injuries or expenses incurred by Plaintiff were not caused by Celebrex®, but
14 were proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or
15 act of God.

16 Eleventh Defense

17 11. Defendants affirmatively deny that they violated any duty owed to Plaintiff.

18 Twelfth Defense

19 12. A manufacturer has no duty to warn patients or the general public of any risk,
20 contraindication, or adverse effect associated with the use of a prescription medical product.
21 Rather, the law requires that all such warnings and appropriate information be given to the
22 prescribing physician and the medical profession, which act as a "learned intermediary" in
23 determining the use of the product. Celebrex® is a prescription medical product, available only
24 on the order of a licensed physician. Celebrex® provided an adequate warning to Plaintiff's
25 treating and prescribing physicians.

26 Thirteenth Defense

27 13. The product at issue was not in a defective condition or unreasonably dangerous
28 at the time it left the control of the manufacturer or seller.

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Fourteenth Defense

14. Celebrex® was at all times material to the Complaint reasonably safe and reasonably fit for its intended use and the warnings and instructions accompanying Celebrex® at the time of the occurrence of the injuries alleged by Plaintiff were legally adequate for its approved usages.

Fifteenth Defense

15. Plaintiff's causes of action are barred in whole or in part by the lack of a defect as the Celebrex® allegedly ingested by Plaintiff was prepared in accordance with the applicable standard of care.

Sixteenth Defense

16. If Plaintiff sustained any injuries or incurred any losses or damages as alleged in the Complaint, the same were caused by the unforeseeable alteration, change, improper handling, abnormal use, or other unforeseeable misuse of Celebrex® by persons other than Defendants or persons acting on its behalf after the product left the control of Defendants.

Seventeenth Defense

17. Plaintiff's alleged damages were not caused by any failure to warn on the part of Defendants.

Eighteenth Defense

18. Plaintiff's alleged injuries/damages, if any, were the result of preexisting or subsequent conditions unrelated to Celebrex®.

Nineteenth Defense

19. Plaintiff knew or should have known of any risk associated with Celebrex®; therefore, the doctrine of assumption of the risk bars or diminishes any recovery.

Twentieth Defense

20. Plaintiff is barred from recovering against Defendants because Plaintiff's claims are preempted in accordance with the Supremacy Clause of the United States Constitution and by the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq.

Twenty-first Defense

21. Plaintiff's claims are barred in whole or in part under the applicable state law because the subject pharmaceutical product at issue was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

Twenty-second Defense

22. The manufacture, distribution and sale of the pharmaceutical product referred to in Plaintiff's Complaint were at all times in compliance with all federal regulations and statutes, and Plaintiff's causes of action are preempted.

Twenty-third Defense

23. Plaintiff's claims are barred in whole or in part by the deference given to the primary jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at issue under applicable federal laws, regulations, and rules.

Twenty-fourth Defense

24. Plaintiff's claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

Twenty-fifth Defense

25. Plaintiff's claims are barred in whole or in part because Defendants provided adequate "direction or warnings" as to the use of the subject pharmaceutical product within the meaning of Comment j to Section 402A of the Restatement (Second) of Torts.

Twenty-sixth Defense

26. Plaintiff's claims are barred or limited to a product liability failure to warn claim because Celebrex® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

Twenty-seventh Defense

27. Plaintiff's claims are barred in whole or in part because the subject pharmaceutical product at issue "provides net benefits for a class of patients" within the meaning of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

Twenty-eighth Defense

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28. Plaintiff's claims are barred under § 4, et seq., of the Restatement (Third) of Torts: Products Liability.

Twenty-ninth Defense

29. To the extent that Plaintiff is seeking punitive damages, Plaintiff has failed to plead facts sufficient under the law to justify an award of punitive damages.

Thirtieth Defense

30. The imposition of punitive damages in this case would violate Defendants' rights to procedural due process under the Fourteenth Amendment of the United States Constitution, Article I, § 17 of the Constitution of the States of Minnesota, and the Constitution of the State of Indiana, and would additionally violate Defendants' right to substantive due process under the Fourteenth Amendment of the United States Constitution.

Thirty-first Defense

31. Plaintiff's claims for punitive damages are barred, in whole or in part, by the Fifth and Fourteenth Amendments to the United States Constitution and are subject to all provisions of Minnesota and Indiana law, including, but not limited to, Minn. Stat. § 549.191 (2006).

Thirty-second Defense

32. The imposition of punitive damages in this case would violate the First Amendment to the United States Constitution.

Thirty-third Defense

33. Plaintiff's punitive damage claims are preempted by federal law.

Thirty-fourth Defense

34. In the event that reliance was placed upon Defendants' nonconformance to an express representation, this action is barred as there was no reliance upon representations, if any, of Defendants.

Thirty-fifth Defense

35. Plaintiff failed to provide Defendants with timely notice of any alleged nonconformance to any express representation.

Thirty-sixth Defense

1 36. To the extent that Plaintiff's claims are based on a theory providing for liability
2 without proof of causation, the claims violate Defendants' rights under the United States
3 Constitution.

4 Thirty-seventh Defense

5 37. Plaintiff's claims are barred, in whole or in part, because the advertisements, if
6 any, and labeling with respect to the subject pharmaceutical products were not false or
7 misleading and, therefore, constitute protected commercial speech under the applicable
8 provisions of the United States Constitution.

9 Thirty-eighth Defense

10 38. To the extent that Plaintiff seeks punitive damages for the conduct which
11 allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by
12 applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due
13 process protections afforded by the United States Constitution, the excessive fines clause of the
14 Eighth Amendment of the United States Constitution, the Commerce Clause of the United States
15 Constitution, and the Full Faith and Credit Clause of the United States Constitution and the
16 Constitutions of the States of Minnesota and Indiana. Any law, statute, or other authority
17 purporting to permit the recovery of punitive damages in this case is unconstitutional, facially
18 and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient
19 standards to guide and restrain the jury's discretion in determining whether to award punitive
20 damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate
21 advance notice as to what conduct will result in punitive damages; (3) permits recovery of
22 punitive damages based on out-of-state conduct, conduct that complied with applicable law, or
23 conduct that was not directed, or did not proximately cause harm, to Plaintiff; (4) permits
24 recovery of punitive damages in an amount that is not both reasonable and proportionate to the
25 amount of harm, if any, to Plaintiff and to the amount of compensatory damages, if any; (5)
26 permits jury consideration of net worth or other financial information relating to Defendants; (6)
27 lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of
28 any punitive damages awards; (7) lacks constitutionally sufficient standards for appellate review

1 of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent,
2 including, without limitation, Pacific Mutual Life Ins. Co. v. Haslip, 499 U.S. 1 (1991), TXO
3 Production Corp. v. Alliance Resources, Inc., 509 U.S. 443 (1993); BMW of North America,
4 Inc. v. Gore, 519 U.S. 559 (1996); and State Farm Mut. Auto Ins. Co. v. Campbell, 538 U.S. 408
5 (2003).

6 Thirty-ninth Defense

7 39. The methods, standards, and techniques utilized with respect to the manufacture,
8 design, and marketing of Celebrex®, if any, used in this case, included adequate warnings and
9 instructions with respect to the product's use in the package insert and other literature, and
10 conformed to the generally recognized, reasonably available, and reliable state of the knowledge
11 at the time the product was marketed.

12 Fortieth Defense

13 40. The claims asserted in the Complaint are barred because Celebrex® was
14 designed, tested, manufactured and labeled in accordance with the state-of-the-art industry
15 standards existing at the time of the sale.

16 Forty-first Defense

17 41. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon
18 information and belief, such injuries and losses were caused by the actions of persons not having
19 real or apparent authority to take said actions on behalf of Defendants and over whom
20 Defendants had no control and for whom Defendants may not be held accountable.

21 Forty-second Defense

22 42. The claims asserted in the Complaint are barred, in whole or in part, because
23 Celebrex® was not unreasonably dangerous or defective, was suitable for the purpose for which
24 it was intended, and was distributed with adequate and sufficient warnings.

25 Forty-third Defense

26 43. Plaintiff's claims are barred, in whole or in part, by the equitable doctrines of
27 laches, waiver, and/or estoppel.

28 Forty-fourth Defense

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1 44. Plaintiff's claims are barred because Plaintiff's injuries, if any, were the result of
2 the pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or
3 illnesses, subsequent medical conditions or natural courses of conditions of Plaintiff, and were
4 independent of or far removed from Defendants' conduct.

5 Forty-fifth Defense

6 45. The claims asserted in the Complaint are barred, in whole or in part, because
7 Celebrex® did not proximately cause injuries or damages to Plaintiff.

8 Forty-sixth Defense

9 46. The claims asserted in the Complaint are barred, in whole or in part, because
10 Plaintiff did not incur any ascertainable loss as a result of Defendants' conduct.

11 Forty-seventh Defense

12 47. The claims asserted in the Complaint are barred, in whole or in part, because the
13 manufacturing, labeling, packaging, and any advertising of the product complied with the
14 applicable codes, standards and regulations established, adopted, promulgated or approved by
15 any applicable regulatory body, including but not limited to the United States, any state, and any
16 agency thereof.

17 Forty-eighth Defense

18 48. The claims must be dismissed because Plaintiff would have taken Celebrex®
19 even if the product labeling contained the information that Plaintiff contends should have been
20 provided.

21 Forty-ninth Defense

22 49. The claims asserted in the Complaint are barred because the utility of Celebrex®
23 outweighed its risks.

24 Fiftieth Defense

25 50. Plaintiff's damages, if any, are barred or limited by the payments received from
26 collateral sources.

27 Fifty-first Defense

28 51. Defendants' liability, if any, can only be determined after the percentages of

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responsibility of all persons who caused or contributed toward Plaintiff's alleged damages, if any, are determined. Defendants seek an adjudication of the percentage of fault of the claimants and each and every other person whose fault could have contributed to the alleged injuries and damages, if any, of Plaintiff.

Fifty-second Defense

52. Plaintiff's claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

Fifty-third Defense

53. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 et seq., and regulations promulgated there under, and Plaintiff's claims conflict with the FDCA, with the regulations promulgated by FDA to implement the FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations, and with the specific determinations by FDA specifying the language that should be used in the labeling accompanying Celebrex®. Accordingly, Plaintiff's claims are preempted by the Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the United States.

Fifty-fourth Defense

54. Plaintiff's misrepresentation allegations are not stated with the degree of particularity required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

Fifty-fifth Defense

55. Plaintiff's claim for punitive damages is barred pursuant to Minn. Stat. § 549.191.

Fifty-sixth Defense

56. Plaintiff's claims are barred and/or limited by the provisions of the Indiana Products Liability Act, I.C. 34-20-1-1 et seq.

Fifty-seventh Defense

57. Plaintiff's damages, if any, are barred or limited by the payments received from

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1 collateral sources, and the provisions of I.C. 34-44-1-1.

2 Fifty-eighth Defense

3 58. Defendants assert all affirmative defenses applicable under the Indiana Products
4 Liability Act, I.C. 34-20-1-1 et seq., and all amendments thereto.

5 Fifty-ninth Defense

6 59. Plaintiff's alleged injuries/damages, if any, were the result of unforeseeable
7 alterations, improper handling, or other unforeseeable misuse of the product Celebrex® by
8 persons other than Defendants or persons acting on its behalf and any liability of Defendants is
9 therefore barred.

10 Sixtieth Defense

11 60. Plaintiff's fraud based claims, if any, are not stated with particularity as required
12 by Rule 9 of the Federal Rules of Civil Procedure and/or Trial Rule 9(B) of the Indiana Rules of
13 Trial Procedure.

14 Sixty-first Defense

15 61. Plaintiff's damages, if any, must be reduced by the percentage of fault attributable
16 to Plaintiff, and to nonparties as provided by Indiana code 34-51-2-1 et seq.

17 Sixty-second Defense

18 62. Defendants reserve the right to supplement their assertion of defenses as they
19 continue with their factual investigation of Plaintiff's claims.

20 V.

21 JURY DEMAND

22 Defendants hereby demand a trial by jury.

23 VI.

24 PRAYER

25 WHEREFORE, Defendants pray that Plaintiff takes nothing by this suit, that
26 Defendants be discharged with their costs expended in this matter, and for such other and further
27
28

1 relief to which they may be justly entitled.

2
3
4 Dated: May 23, 2008

GORDON & REES LLP

5
6 /s/

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

IN RE BEXTRA AND CELEBREX
MARKETING, SALES PRACTICES AND
PRODUCTS LIABILITY LITIGATION

This document relates to

TIM GRAY,

Plaintiff,

vs.

PFIZER, INC., PHARMACIA CORPORATION,
G.D. SEARLE LLC and MONSANTO
COMPANY,

Defendants.

) MDL Docket No. 1699
)
) CASE NO. 3:08-cv-01434-CRB

) **RULE 7.1 STATEMENT**

) **JURY TRIAL DEMANDED**

Pursuant to Federal Rule of Civil Procedure 7.1, Defendants Pfizer Inc. ("Pfizer"),
Pharmacia Corporation ("Pharmacia"), and G.D. Searle LLC ("Searle") submit this their
Corporate Disclosure Statement. Defendants Pfizer, Pharmacia and Searle state:

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1. Defendant Pfizer Inc. does not have any parent corporations, and no publicly traded company owns 10% or more of Pfizer Inc.'s stock.
2. Defendant Pharmacia Corporation is a wholly-owned subsidiary of Defendant Pfizer Inc.
3. Defendant G.D. Searle LLC is a limited liability company whose sole member is Pharmacia & Upjohn Company LLC, which is a limited liability company whose sole member is Pharmacia & Upjohn LLC, which is a limited liability company whose sole member is Pharmacia Corporation.

May 23, 2008

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